This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 21-R-0088 | CUSTOMER NO. 339 | FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Pfizer Global Research and Development
Pfizer, Inc.
235 East 42nd Street
New York, New York 10017

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATION(S)*(sites)*

See Attached Listing

RECEIVED
NOV 30 2006
BY:

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	92	2019	768	312	3099
5. Cats	25	602	696	142	1440
6. Guinea Pigs		4730	3378	277	8385
7. Hamsters		31494	1403	8537	41434
8. Rabbits	69	1075	5599	81	6755
9. Non-Human Primates	120	1059	240	16	1315
10. Sheep					
11. Pigs		102	42		144
12. Other Farm Animals					
Horses				55	55
13. Other Animals					
Ferrets		39	39	2	80
Gerbils		974	249	716	1939
Degus			69		69

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE

(b)(6), (b)(7)c

OFFICIAL *(Type or Print)*

DATE SIGNED 11/20/06

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(AUG 91) ... which is obsolete

PART 1 - HEADQUARTERS

USDA Annual Report of Research Facility - 2006
USDA APHIS Form 7023
Facility Locations
Registration Number: 21-R-0088
Customer Number: 339

Facility: Pfizer Global Research and Development
235 East 42nd Street
New York City, NY 10017

Telephone (b)(2)High, (b)(7)f

Pfizer Global Research and Development (PGRD)
(b)(2)High, (b)(7)f
Attending Veterinarian:
(b)(6), (b)(7)c

Pfizer Global Research and Development (PGRD)
(b)(2)High, (b)(7)f
Attending Veterinarian:
(b)(6), (b)(7)c

Pfizer Global Research and Development (PGRD)
(b)(2)High, (b)(7)f
Attending Veterinarian :
(b)(6), (b)(7)c

Pfizer Global Research and Development (PGRD)
(b)(2)High, (b)(7)f
Attending Veterinarian:
(b)(6), (b)(7)c

Pfizer Global Research and Development
(b)(2)High, (b)(7)f
Attending Veterinarian:
(b)(6), (b)(7)c

(b)(2)High, (b)(7)f
Attending Veterinarian:
(b)(6), (b)(7)c

(b)(2)High, (b)(7)f Attending Veterinarian: (b)(6), (b)(7)c	(b)(2)High, (b)(7)f Attending Veterinarian: (b)(6), (b)(7)c

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Attachment 1

Summary of IACUC Approved Exceptions Permitted by the Standards and Regulations
For the 2005-2006 Annual Report of Research Facility, #21-R-0088
Pfizer Global Research and Development
Ann Arbor, MI; Groton, CT; Kalamazoo, MI; La Jolla, CA; St. Louis, MO;
Esperion Therapeutics, Ann Arbor, MI; PGM Lincoln, NE; PGM Omaha, NE

Pain/Distress Exceptions

Each of the following Animal Care and Use Procedures (ACUP) involved studies in which animals could have experienced pain and/or distress. The test substances being evaluated are novel compounds; consequently, data on how these compounds react in the animal model and with other chemical entities is very limited or non-existent. Therefore, the use of analgesics or other pain-relieving agents could defeat the objectives of the research by directly interfering with the end point parameter being measured. This interference could give results that are not reliable which would lead to repeating the studies, thus requiring the need to use more animals. For this reason, the Institutional Animal Care and Use Committees (IACUC) granted an exception for each. Any incident of pain or distress was limited in duration to that scientifically necessary. In actual practice, many animals involved in such studies were not observed by the investigator to experience pain and/or distress.

Species: **Dogs**

A. The study objective was to assess safety/toxicity evaluations, the results of which will be used to support registration of Pfizer proprietary compounds. Studies to characterize the toxicity of new pharmaceuticals are required in non-rodent species by all regulatory agencies that review and approve new human medications, and alternative methodologies alone are not sufficient. In a safety evaluation, administration of analgesics is not possible as analgesics may alter the animals' response to the test compound or otherwise confuse interpretation of the study, which would result in a need to repeat studies, using additional animals. However, other nursing and supportive care is provided by the veterinary staff, as indicated. Twenty-six (26) dogs showed signs of pain and/or distress based on investigator observations.

B. The study objective was to assess the potential toxicity of test compounds after administration to a surgical dog model by continuous intravenous infusion for durations between 1 day and 4 weeks at toxicologically relevant doses. Nine (9) dogs showed signs of pain and/or distress based on investigator observations

C. The study objective was to [redacted] in short-term [redacted] One hundred and fifty-nine (159) dogs experienced varying degrees of pain/lameness during the conduct of these studies. In this model, administration of [redacted] other than those being tested) is not possible during the testing regimen, as they may alter the animal's response to the test compound. Analgesics are administered post-procedurally as indicated.

D. The study objective was to evaluate the efficacy of nove [redacted] compounds in a canine model of [redacted] Twenty-eight (28) dogs became febrile and developed cougning associated with [redacted] with a duration ranging from 1 to 6 days. This experimentally induced condition was necessary to provide an accurate model in which to test compounds designed to provide therapeutic benefit. Administration of analgesic drugs could alter the animals' response to the test compounds or otherwise confuse interpretation of the study, which would result in a need to repeat studies, using additional animals. The potential for confused interpretation is particularly a concern in [redacted] studies, where masking of clinical signs with pain relievers or anti-inflammatory drugs may provide false information on test article efficacy. However, in these situations, other supportive and nursing care is provided as indicated.

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E. The study objective was to [redacted] challenged with [redacted] after being [redacted] Fifty-nine (59) dogs experienced [redacted] with increased [redacted] Antibiotics and analgesics were not administered as they may have altered the animals' responses to the challenge organism.

Species: Cats

F. The study objective was to assess the [redacted] in a short-term [redacted] Fifty-nine (59) cats experienced varying degrees of pain/lameness during conduct of these studies. In this model, administration of [redacted] (other than those being tested) is not possible during the testing regimen, as they may alter the animal's response to the test compound. However, these agents, as well as other nursing and supportive care, are provided post-procedurally by the veterinary staff, as indicated.

G. The study objective was to evaluate the efficacy of nove[redacted] in a feline model of [redacted] Seventy-two (72) cats were used in various models of [redacted] to evaluate the efficacy of novel therapeutic compounds. Reactions in these animals ranged from [redacted] and/or [redacted] These experimentally induced conditions were necessary to provide accurate models in which to test compounds designed to provide therapeutic benefit. The potential for confused interpretation is particularly a concern in [redacted] studies, where masking of clinical signs with pain relievers or anti-inflammatory drugs may provide false information on test article efficacy. However, in these situations, other supportive and nursing care is provided as indicated.

H. The study objective was to model the development of [redacted] One (1) cat actually developed signs of this condition and was euthanized. Two (2) cats experienced [redacted] and one (1) cat became somewhat anemic. This experimentally induced condition was necessary to provide an accurate model in which to test compounds designed to provide therapeutic benefit. Although administration of analgesic drugs could alter the animals' response to the test compounds or otherwise confuse interpretation of the study, supportive and nursing care was provided as indicated.

I. The study objective was the evaluation of the [redacted] in [redacted] cats subjected to [redacted] One (1) animal was euthanized with [redacted] in [redacted] identified at necropsy. Another animal was euthanized due to poor clinical health.

J. The study objective was the evaluation of the [redacted] cats subjected to [redacted] One cat was found dead and was submitted for necropsy. [redacted] were identified.

K. The study objective was to identify the effect of [redacted] on protection against [redacted] Two (2) cats died and one (1) cat was euthanized with all submitted to necropsy. Necropsy results indicated [redacted] by [redacted]

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Esperion Therapeutics, Ann Arbor, MI; PGM Lincoln, NE; PGM Omaha, NE

Species: Guinea Pigs

L. The study objective was to determine the potency of [redacted] in guinea pigs as outlined in Code of Federal Regulations (CFR, 2004) [redacted]. The tests are required by regulation as proof of [redacted] in each serial of vaccine produced. Death in this test has been used for many years to indicate lack of protection from [redacted] The rapid progression of the disease in the guinea pig makes intervention before death difficult. However, humane endpoint intervention is now allowed and one hundred and thirty-one (131) guinea pigs were removed from studies before they died. The guinea pigs were euthanized as soon as it was determined they could not survive. However, one hundred and forty-four (144) animals died during the study. Survival would likely be impacted by the use of analgesics or anti-inflammatory drugs, although the exact effects are not known. Use of drugs, therefore, is expected to invalidate the scientific value of the protection endpoint. For this reason drugs are not administered to reduce pain or distress.

Species: Hamsters

M. The study objective was to determine the potency of [redacted] in hamsters as outlined in [redacted] including [redacted] The tests are required by regulation as proof of [redacted] vaccine potency in each serial of vaccine produced. Because the vaccine is given at a fractional dose, the test amounts to a protective endpoint determination for the vaccine being tested. Death in this test has been used for many years to indicate lack of protection from [redacted]. The rapid progression of the disease in the hamster makes intervention before death difficult. However, humane endpoint intervention is now allowed with six hundred and thirty-three (633) hamsters were removed from the studies before they died. The hamsters were euthanized as soon as it was determined they could not survive. However, seven thousand eight hundred and eight-nine (7889) animals died before euthanasia. Survival would likely be impacted by the use of analgesics or anti-inflammatory drugs, although the exact effects are not known. Use of drugs, therefore, is expected to invalidate the scientific value of the protection endpoint.

N. The study objective was to evaluate the [redacted] disease. Fourteen (14) animals developed signs of pain or distress as a consequence of the study and were either treated or euthanized.

Species: Rabbits

O. The study objective was to assess the [redacted] of a variety of test [redacted] Two (2) rabbits showed variable signs of pain/distress and were humanely euthanized.

P. The study objective was to evaluate the [redacted] in a rabbit model of [redacted] Analgesics cannot be used throughout the test period because they may directly affect [redacted] important to the study or [redacted] which would complicate evaluation. Thirty-eight (38) animals showed signs of pain and/or distress based on investigator observations.

Q. The study objective was to evaluate [redacted] for the treatment and/or prevention of [redacted] model enhanced with the [redacted] Thirty-four (34) animals showed signs of pain and/or distress based on investigator observations.

Species: Nonhuman Primates

R. The study objective was to assess the potential toxicity of various test compounds in the [redacted] to support [redacted]. Fifteen (15) animals experienced treatment-related [redacted] Nursing and supportive care was provided by the veterinary staff, as indicated; animals that were unresponsive to treatment were euthanized.

Other Farm Animals

Species: Horses

S. These animals were used in an [redacted] procedure for the production of a [redacted] This product is currently the treatment of choice for [redacted] and is also an important [redacted] The procedure involves the use of [redacted] as part of ar [redacted] as required in the outline of manufacture. Fifty-five (55) horses experienced a superficial reaction to the [redacted] administered. Appropriate nursing and supportive care was provided as indicated, but the product license does not permit any deviation from the outline of manufacture during the course of the protocol, including the administration of analgesics.

Other Animals

Species: Ferrets

T. The study objective was to discover [redacted] for the treatment and/or prevention of [redacted] Two (2) animals showed signs of pain and /or distress based on investigator observations

Species: Gerbils

U. The study objective was to discover and develop [redacted] for the prevention or treatment of a variety of [redacted] Specifically, to evaluate the [redacted] of new or known compounds against [redacted] Seven Hundred (700) animals showed signs of pain and /or distress based on investigator observations

V. The study objective was to discover and develop [redacted] that have [redacted] Sixteen (16) animals showed signs of pain and /or distress based on investigator observations

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IACUC EXEMPTIONS TO STANDARDS AND REGULATIONS UNDER THE ANIMAL WELFARE ACT

1. Following a 5-week observation by IACUC members and the Attending Veterinarian, the IACUC approved a request to house hamsters (singly) in ventilated cages that were ¼ inch in height less than required by Animal Welfare Regulations (AWA)[§3.28]. During the observation period members noted that all animals were able to make normal postural adjustments and had adequate floor space (19 in^2) to move about freely. One thousand and seven hundred and sixty-nine (1769) animals were housed in these cages.

2. The IACUC has approved an exemption such that cat enclosures are not cleaned and sanitized every two weeks. This involved three hundred and thirty-six (336) cats during this reporting period. These cats were on studies involving [redacted] Because of the risk of contaminating other rooms if the cats were moved during sanitization, the rooms were only sanitized between studies (every 6-12 weeks). Granting an exception from the two-week sanitization schedule had little effect on the living conditions of the animals. The rooms and runs were washed down each day.

DOG EXEMPTIONS FROM EXERCISE BY PROTOCOL

1. During [redacted] studies, animals were housed in [redacted] necessitating limited exemptions from the exercise plans when [redacted] were used or when [redacted] were to be collected. These exemptions were generally short term (72 hours or less), but in a few cases involved longer periods (7-10 days). Forty-Seven (47) animals were exempted from the exercise program during [redacted]

2. The study objective was to evaluate the [redacted] in dogs. A [redacted]. Because of this instrumentation, ninety (90) dogs were exempted from the IACUC approved dog exercise plan.

DOG EXEMPTIONS FROM EXERCISE BY VETERINARIAN

1. Six (6) dogs were exempted from exercise during the post-operative healing period [redacted] These animals were exempted from [redacted] for a 14-day recovery period, after which time they were able to resume normal activity.

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NONHUMAN PRIMATE EXEMPTIONS FROM PAIR HOUSING/ENVIRONMENTAL ENRICHMENT

1. Two (2) squirrel monkeys were exempted from pair housing due to aggressive behavior towards cage mate. The animals did have visual and auditory contact with other monkeys and was provided all other enrichment opportunities.

2. Forty-five (45) macaques were housed individually during [redacted] studies. Single housing was necessary because the [redacted] time. However, in non-study periods, the animals were pair housed.

3. Fifty-nine (59) macaques were exempted from pair housing due to aggressive behavior towards cage mate. These monkeys did have visual and auditory contact with other monkeys.

4. During [redacted] studies, animals were housed in [redacted] cages, necessitating limited exemptions from the [redacted] for these species when [redacted] were used or when [redacted] These exemptions were generally short term (72 hours or less), but in a few cases involved longer periods (7-10 days). Eighteen (18) macaques did not receive [redacted] throughout this study period.

5. Ten (10) Cynomolgus monkeys were exempted from pair housing due to [redacted] Monkeys did have visual and auditory contact with other monkeys and was provided all other enrichment opportunities

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Attachment 2
Explanation for Animals Listed in Category E - APHIS Form 7023
For the 2005-2006 Annual Report of Research Facility, #21-R-0088
Pfizer Global Research and Development
Ann Arbor, MI; Groton, CT; Kalamazoo, MI; La Jolla, CA; St. Louis, MO; Esperion Therapeutics, Ann Arbor, MI; PGM Lincoln, NE; PGM Omaha, NE

Testing of proprietary compounds is conducted in animals to discover new human therapeutics and in response to federal regulatory requirements for safety evaluation of pharmaceuticals prior to human clinical trials. There are similar requirements prior to clinical trials of animal health products in food animals and companion animals. On occasion, the proprietary compounds cause unexpected pain or distress which cannot be foreseen, but which is nevertheless considered during the IACUC's review/approval process as stated in Attachment 1. Frequently, the use of pain relieving drugs is not scientifically appropriate in product safety assessment.

These studies are designed in accordance with the safety testing guidelines described in the following publications:

1. Code of Federal Regulations (CFR, 2002), Title 21, Chapter I, Part 58 (Good Laboratory Practices for Nonclinical Laboratory Studies).
2. Code of Federal Regulations (CFR, 2004) Title 9, Chapter 1, Part 113.106, Clostridium Chauvoei Bacterin & Part 113.107, Clostridium Haemolyticum Bacterin.
3. Code of Federal Regulations (CFR, 2004) Title 9, Chapter 1, Part 113.101, Leptospira Pomona Bacterin; Part 113.102, Leptospira Icterohaemorrhagiae Bacterin; 113.103, Leptospira Canicola Bacterin & 113.104, Leptospira Grippotyphosa Bacterin.
4. Code of Federal Regulations – (CFR 511 - New Animal Drugs for Investigational Use), (CFR 514 - New Animal Drug Applications)

There are also occasions when pain-relieving drugs cannot be used in drug discovery studies. In the following cases, pain-relieving drugs were not used because they would have adversely affected the scientific validity of the study. Any incident of pain or distress was limited in duration to that scientifically necessary. The numbers provided below reflect animals that experienced unrelieved pain and/or distress and were identified in the ACUP exceptions described in Attachment 1.

Also identified below with *, are animals that experienced pain/distress due to an unexpected compound or procedure reaction.

** Removed From Study (RFS)
** Remained on Study (ROS) but received nursing/supportive care (i.e. fluids, special diets, or other non-chemical interventions)

Species	Incident	Number Affected	IACUC Approved Exceptions (see Attachment 1)	Safety Guidelines as Described in Publications Listed Above	Unexpected Pain/Distress Resolution/Action
Dogs	[redacted]	13	A ROS - Treated	1	
Dogs		8	A ROS - Treated	1	
Dogs		2	A RFS - Euthanized	1	
Dogs	[redacted]	3	A RFS - Euthanized	1	
Dogs		9	B ROS - Treated	1	

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Pfizer Global Research and Development
Ann Arbor, MI; Groton, CT; Kalamazoo, MI; La Jolla, CA; St. Louis, MO; Esperion Therapeutics, Ann Arbor, MI; PGM Lincoln, NE; PGM Omaha, NE

Species	Incident	Number Affected	IACUC Approved Exceptions (see Attachment 1)	Safety Guidelines as Described in Publications Listed Above	Unexpected Pain/Distress Resolution/Action
Dogs	[redacted]	159	C ROS - Treated	1	
Dogs		26	D ROS	1	
Dogs		2	D RFS - Euthanized	1	
Dogs		59	E ROS	4	
Dogs		4			ROS - Treated
Dogs		16			ROS - Treated
Dogs		6			RFS - Euthanized
Dogs		5			ROS - Treated
	Total	**312**			
Cats	[redacted]	59	F ROS	4	
Cats		32	G ROS	4	
Cats		40	G RFS - Euthanized	4	
Cats		1	H RFS - Euthanized	4	
Cats		3	H ROS	4	
Cats		2	I RFS – Euthanized	4	
Cats		1	J	4	

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Explanation for Animals Listed in Category E - APHIS Form 7023
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Ann Arbor, MI; Groton, CT; Kalamazoo, MI; La Jolla, CA; St. Louis, MO; Esperion Therapeutics, Ann Arbor, MI; PGM Lincoln, NE; PGM Omaha, NE

Species	Incident	Number Affected	IACUC Approved Exceptions (see Attachment 1)	Safety Guidelines as Described in Publications Listed Above	Unexpected Pain/Distress Resolution/Action
	[redacted]		RFS - Died		
Cats		3	K RFS – Euthanized/Died	4	
Cats		1			ROS - Treated
		142			
Guinea Pigs		275	L RFS- Euthanized/Died	2	
Guinea Pigs		2			RFS-Euthanized
		277			
Hamsters		8109	M RFS – Euthanized/Died	3	
Hamsters		413	M RFS – Euthanized	3	
Hamsters		7	N ROS – Treated	1	
Hamsters		7	N RFS – Euthanized	1	
Hamsters		1			RFS - Euthanized
	Total	**8537**			
Rabbits	[redacted]	2	O RFS - Euthanized	1	
Rabbits		38	P ROS – no treatment	1	
Rabbits		34	Q ROS – no treatment	1	
Rabbits		5			RFS - Euthanized

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Attachment 2
Explanation for Animals Listed in Category E - APHIS Form 7023
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Pfizer Global Research and Development
Ann Arbor, MI; Groton, CT; Kalamazoo, MI; La Jolla, CA; St. Louis, MO; Esperion Therapeutics, Ann Arbor, MI; PGM Lincoln, NE; PGM Omaha, NE

Species	Incident	Number Affected	IACUC Approved Exceptions (see Attachment 1)	Safety Guidelines as Described in Publications Listed Above	Unexpected Pain/Distress Resolution/Action
Rabbits		2			RFS - Died
	Total	**81**			
Nonhuman Primates		15	R ROS - Treated	1	
Nonhuman Primates		1			ROS – no Treatment
	Total	**16**			
Horses		55	S ROS	1	
	Total	**55**			
Ferrets		2	T RFS – Euthanized	1	
	Total	**2**			
Gerbils		700	U RFS - Euthanized	1	
Gerbils		16	V ROS - Treated	1	
	Total	**716**			